



UNITED STATES PATENT AND TRADEMARK OFFICE

79
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,891	01/05/2004	Holger Puchta	532622003100	2084

7590 03/22/2006
Roberte M. D. Makowski
Connolly Bove Lodge & Hutz LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/750,891		PUCHTA ET AL.	
	Examiner		Art Unit	
	Cynthia Collins		1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 5, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-4, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- II. Claim 5, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- III. Claim 6, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- IV. Claim 7, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- V. Claim 8, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- VI. Claims 9-10, drawn to a recombination system, classified in class 435, subclass 320.1, for example.
- VII. Claims 12-13, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- VIII. Claim 14, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- IX. Claim 15, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.

Art Unit: 1638

- X. Claim 16, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 800, subclass 291, for example.
- XI. Claim 17, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- XII. Claim 18, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- XIII. Claim 19, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- XIV. Claim 20, drawn to a method for removing a DNA sequence from chromosomal DNA of a eukaryotic cell, classified in class 435, subclass 463, for example.
- XV. Claims 22-25, drawn to a plant, classified in class 800, subclass 298, for example.
- XVI. Claims 22 and 25, drawn to a yeast, classified in class 435, subclass 254.2, for example.
- XVII. Claims 22 and 25, drawn to an alga, classified in class 435, subclass 257.2. , for example.
- XVIII. Claims 22 and 25, drawn to a fungus, classified in class 435, subclass 254.11. , for example.
- XIX. Claims 22 and 25, drawn to an animal, classified in class 800, subclass 8, for example.
- XX. Claim 26, drawn to a method for the production of a product, classified in class 800, subclass 8, for example.

Art Unit: 1638

For inventions I, II, VII, IX and X above, restriction to a single element is also required under 35 USC 121. Therefore, upon election of any of inventions I, II, VII, IX and X, a single element must also be elected.

For inventions III, IV, V, VI, XI, XII and XIV above, restriction to a single enzyme is also required under 35 USC 121. Therefore, upon election of any of inventions III, IV, V, VI, XI, XII and XIV, a single enzyme must also be elected.

For invention XX above, restriction to a single product produced is also required under 35 USC 121. Therefore, upon election of invention XX, a single product produced must also be elected.

Applicants are reminded that nucleotide sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Art Unit: 1638

Claim 1 link(s) inventions I-VI. Claim 11 link(s) inventions VII-XIV. Claim 21 link(s) inventions XV-XIX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 11 or 21. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The products of inventions I-VI comprise constructs comprising structurally and functionally distinct components in different arrangements. The constructs comprised by the products of inventions I-VI comprise elements and enzymes that differ from each other in both

Art Unit: 1638

structure and specific activities. The products of inventions I-VI differ in structure, function and classification from the products of inventions XV-XIX.

Inventions I-VI and inventions VII-XIV and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the recombination system can be used in a materially different process of using that product, such as a hybridization method.

The methods of inventions VII-XIV utilize structurally and functionally distinct materials. The methods of inventions VII-XIV do not require the use of or result in the production of the products of inventions XV-XIX. The methods of inventions VII-XIV result in the product of products that are different from the products produced by the methods of invention XX.

The products of inventions XV-XIX differ in structure and in physiology and in both patent and taxonomic classification. The products of inventions XV-XIX are not required to practice or produced by the methods of invention XX.

The methods of invention XX are distinct methods because they produce products that differ in both structural and physical properties:

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their recognized divergent subject matter, and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

Art Unit: 1638

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Art Unit: 1638

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC



3/16/06